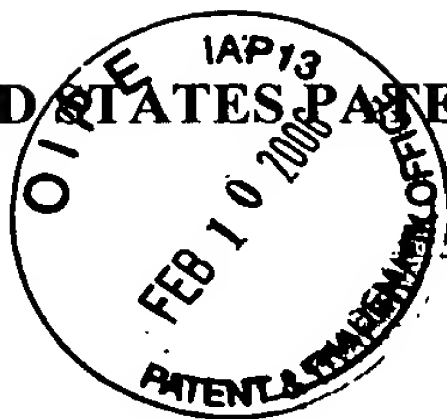


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



15  
1615  
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In re Application of:

Wolfgang HEIL et al.

Confirmation No.: 7991

Serial No.: 09/757,688

Examiner: L.S. Channavajjala

Filed: January 11, 2001

Group Art Unit: 1615

Title: DROSPIRENONE FOR HORMONE REPLACEMENT THERAPY

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

**TIMING AND FEES**

- ☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
  - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
  - ☐ before the mailing of a first substantive office action (including after filing of an RCE).
- ☒ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- ☒ a final rejection under 37 C.F.R. § 1.113;
  - ☒ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - ☒ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

02/13/2006 SZEWDIE1 00000072 09757688

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180.00 OP

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
- ☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:
- ☐ a final action under 37 C.F.R. § 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
- ☐ a notice of allowance under 37 C.F.R. § 1.311;
- AND is filed on or before payment of the issue fee; AND is accompanied by:
- ☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

**STATEMENTS UNDER 37 C.F.R. 1.97(e)**

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

**CITED MATERIALS**

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- ☒ Copies of the materials listed are attached.

**NON-ENGLISH LANGUAGE REFERENCES**

- ☐ A translation of the Non-English language document is provided.
- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone  
Y = document of particular relevance when it is combined with another such document  
A = document defining the general state of the art  
O = non-written disclosure  
P = intercalated document  
T = document cited to understand the theory or principle underlying the invention  
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date  
D = cited in the application  
L = cited for another reason  
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- ☐ Translation of other relevant information on foreign search report

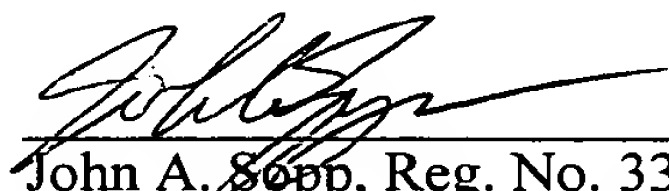
**OTHER INFORMATION**

The cited documents are filings in Civil Action No. 05-02308 which includes a counterclaim for invalidity of U.S. Patent 6,787,531.

**PAYMENT OF FEES DUE (IF ANY):**

- ☒ A check for \$180.00 covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.
- ☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account No. 13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

  
\_\_\_\_\_  
John A. Sopp, Reg. No. 33,103  
Attorney for Applicants

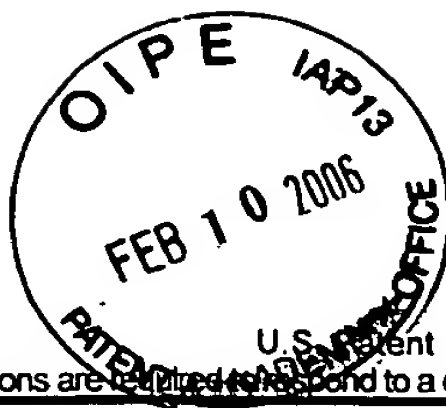
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Date: February 10, 2006



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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

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of

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### Complete if Known

Application Number	09/757,688
Filing Date	January 11, 2001
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1615
Examiner Name	L.S. Channavajjala
Attorney Docket Number	PLOVIN-2A

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		K. Fotherby, et al. "Review: The new low dose oral contraceptives", Journal of Obstetrics and Gynecology, Vol. 14, (1994), pgs. 327-332.	
		L. Speroff, "Review: Evaluation of a new generation of oral contraceptives", The Amer. College of Obstetricians & Gynecologists, Vol. 81, No. 6, (1993), pgs. 1034-1047.	
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		J. Endrikat, et al., "A Twelve-Month Comparative Clinical Investigation...." Elsevier Science Inc., (1995), pgs. 229-235.	
		D. Mishell, et al., "Postmenopausal hormone replacement with a combination estrogen-progestin regimen for five days per week", The Journal of Reproductive Medicine, Inc., Vol. 36, No. 5, (1991), pgs. 351-355.	
		S. Sipinen, et al., "Pharmacokinetic studies on low dose estradiol 17β administered orally to postmenopausal women", Acta Obstet Gynecol Scand 59, (1980), pgs. 515-518.	
		J. M. Aitken, et al., "Oestrogen replacement therapy for prevention of osteoporosis after oophorectomy", British Medical Journal, (1973), pgs. 370-375.	
		C. Hassager, et al., "Estrogen/Gestagen therapy changes soft tissue body composition in postmenopausal women", Metabolism, Vol. 38, No. 7, (1989), pgs. 662-665.	
		Ch. Egarter, et al., "Ovarian function during low-dose oral contraceptive use", Elsevier Science Inc., (1995).	
		J. Spona, et al., "Efficacy of low-dose oral contraceptives containing levonorgestrel, gestoden and cyproterone acetate", "Gynecol, obstet, Invest., Vol. 23, (1987), pgs. 184-193.	
		The Writing Group for PEPI Trial, "Effects of hormone replacement therapy on endometrial histology in postmenopausal women", Hormone Replacement Therapy, Vol. 275, No. 5, (1996) pgs. 370-375.	

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.